Complete Summary

GUIDELINE TITLE

Gastric cancer.

BIBLIOGRAPHIC SOURCE(S)

Gastric cancer. Philadelphia (PA): Intracorp; 2005. Various p. [18 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from April 1, 2005 to April 1, 2007.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Gastric cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Oncology
Surgery

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of gastric cancer that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with gastric cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests:
    - Fecal occult blood test
    - Upper gastrointestinal endoscopy
    - Endoscopic ultrasound
    - Upper gastrointestinal x-rays
    - Colonoscopy
    - Computed tomography (CT) of abdomen and chest
    - Laparotomy
    - Magnetic resonance imaging (MRI)
    - Blood tests (alpha-fetoprotein level, complete blood count, liver function tests)
    - Tumor markers

Management/Treatment

1. Surgery
    - En block resection
    - Distal gastrectomy
    - Proximal gastrectomy
    - Esophagogastric resection
    - Lymph node dissection

2. Combination of chemotherapy and radiation therapy
3. Physical therapy
4. Referral to specialists
5. Supportive care
6. Case management strategies, including case initiation, case management focus, and discharge

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Effectiveness of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

<u>Diagnostic Confirmation</u>

Subjective Findings

- Unintentional weight loss (most frequent)
- Abdominal pain
- Nausea
- Anorexia
- Weakness
- Dysphagia
- Tarry stools
- Early satiety
- Lower extremity edema

Objective Findings

- Palpable epigastric mass
- Palpable supraclavicular node(s)
- Hepatomegaly with ascites
- Acute upper gastrointestinal bleeding with
    - Melena
    - Hematemesis
- Postprandial vomiting suggests gastric outlet obstruction
    - Foul-smelling emesis
- Cachexia
- Microangiopathic hemolytic anemia
    - A consequence of disseminated intravascular coagulation (DIC)
- Chronic intravascular coagulation
    - Superficial thrombophlebitis or Trousseau's syndrome
- Abnormal liver function tests
- Hypoproteinemia
- Paraneoplastic syndromes
    - Lambert-Eaton myasthenic syndrome
    - Encephalomyelitis
    - Cerebellar degeneration
    - Limbic encephalitis
    - Others
- Membranous nephropathy
- Seborrheic keratoses and dermatomyositis
- Acanthosis nigricans

Diagnostic Tests

- Fecal occult blood test (FOBT)
    - To determine gastrointestinal bleeding at the microscopic level
    - Occult stool testing most efficacious when repeated at least 3 times on different stool samples
    - Test preparation simply to avoid eating foods with peroxidase activity (turnips and horseradish)
- Upper gastrointestinal (UGI) endoscopy; also called gastroscopy or esophagogastroduodenoscopy (EGD)
    - Direct visual exam of the upper gastrointestinal (GI) tract, including esophagus, stomach, and duodenum, is considered much more sensitive and specific than UGI x-rays.
    - Viewing (video images or "still pictures"), air insufflation or fluid aspiration

    - Biopsy performed via endoscopy for cytologic and histologic testing
    - Therapeutic procedures can be performed, if necessary:
        - Coagulation probes or passage of sclerosing agents to quell active GI bleeding
        - Laser beam surgery to obliterate tumors or polyps
    - Contraindications include esophageal wall diverticula, suspected GI tract perforation, recent GI surgery, and severe UGI bleeding
- Endoscopic ultrasound (EUS)
    - High degree of accuracy in determining depth of tumor invasion (extension beyond muscularis propria)
    - Less accurate in detecting regional lymph node metastases
    - Ultrasound-guided fine needle aspiration (FNA) can be used to enhance ability of EUS to determine tumor stage and respectability.
- Upper gastrointestinal x-rays
    - Although UGI x-rays with contrast dye can readily identify mass to help rule out malignancy in symptomatic patients, UGI endoscopy is considered more efficacious as specific findings are obtained.
- Colonoscopy (see the Intracorp guideline Colonoscopy)
    - Scopic visual examination of the lower colon and rectum detects early polypoid tumors preoperatively.
    - Also useful in post-resection surveillance
    - Multiple biopsies may be performed to increase study sensitivity.
- Computed tomography (CT) scan
    - Abdomen alone for gastric lesion
    - Include chest as well for lesions at the gastroesophageal junction
    - CT is used to identify extragastric metastases
- Laparotomy
    - Laparotomy may be used when metastases to omentum and liver is suspected.
    - Commonly used to assess for distant metastasis or unresectable locally advanced abdominal cancers.
- Magnetic resonance imaging (MRI)
    - MRI may have a future use in staging, especially as organ-specific dyes evolve.
- Blood tests that may be ordered:
    - Alpha-fetoprotein level (AFP)
        - Although generally not useful for early detection purposes, AFP may have diagnostic value in gastric cancer.
    - Complete blood count (CBC)
        - May reveal iron deficiency anemia or anemia of chronic disease
    - Liver function tests (LFT)
        - May be 1abnormal in metastatic spread
- Tumor markers:
    - CA19-9 carbohydrate antigen (CA)- Normal CA19-9 value: less than 37 U/mL
        - The protein CA may show increases in gastric cancer, but may also be increased in cholecystitis, cirrhosis, cystic fibrosis, gallstones, and pancreatitis.
    - Tissue polypeptide antigen (TPA). Normal TPA value: 80 to 100 U/L in serum
        - TPA may also be detected in urine, tissue washings, and effusions.

        - TPA elevations occur in diseases other than cancer, such as cholangitis, cirrhosis, hepatitis, pneumonia, or urinary tract infection (UTI).
        - The presence of several peptides listed has poor implication for prognosis.
        - Estrogen receptor, epidermal growth factor receptor, the e-erb-b2 protein, and plasminogen activator inhibitor type 1
    - Carcinoembryonic antigen level (CEA); Normals: 0 to 2.5 mg/mL; up to 10 mg/mL in smokers
        - CEA is useful in establishing diagnosis and recurrence for tumors that secrete this substance and in following disease progression.
        - Because colon lesions are not likely to secrete CEA, it is not a highly reliable indicator of colon cancer.
        - If CEA is elevated, return to normal levels is expected to occur within 48 hours after complete tumor excision.

Differential Diagnosis

- Upper gastrointestinal bleeding (UGIB), from
    - Peptic ulcer disease [PUD] (see the Intracorp guideline Peptic Ulcer Disease)
    - Gastritis (see the Intracorp guideline Gastritis)
    - Zollinger-Ellison syndrome
    - Stress ulceration
    - Ménétrier's disease
    - Corrosive gastritis
- Kaposi's sarcoma, particularly with acquired immune deficiency syndrome (AIDS)
- Carcinoids
- Metastases to the stomach from other primary cancer
    - Breast, melanoma, and lung are the most common.
- Leiomyomas
- Abdominal lymphoma (see the Intracorp guideline Non-Hodgkin's Lymphoma)
- Fibromas
- Neurofibromas
- Gastric volvulus
- Superior mesenteric artery syndrome
- Gastric polyps
- Bezoars

Treatment Options

Surgery

- En bloc resection with negative margins >5 cm all around
- Distal gastrectomy for distal tumors
- Proximal gastrectomy for proximal tumors
- Esophagogastric resection for tumors that approach gastroesophageal junction
- Lymph node dissection of from 15 to up to 30 nodes for complete staging
    - May not significantly impact survival

- Splenectomy should be avoided unless involved by tumor.
    - Care Setting: acute inpatient (see the Intracorp procedure guideline Gastrectomy)
- After curative resection, adjuvant combination chemotherapy and radiation therapy should be offered to node (+) patients, or those with full thickness tumors (see the Intracorp guideline Chemotherapy).
    - Care Setting: clinic or free-standing outpatient, physician's office, or home care; unless acute illness/deconditioning warrant acute inpatient, subacute/skilled nursing facility inpatient, or hospice inpatient care setting
- Supportive care, radiation, or chemotherapy alone are treatment alternatives for patients with metastatic disease and/or those for whom surgery poses a greater risk than benefit.

Duration of Medical Treatment

- Medical - Optimal: 7 day(s), Maximal: 28 day(s)
    - Gastrectomy may result in cure in early-stage cases.
    - Gastric cancer is often a terminal illness with care needs for the remainder of the patient's lifetime.

Additional information regarding primary care visit schedules, referral options, specialty care, physical therapy, and durable medical equipment is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Post endoscopy
- Chemo/radiation therapy
- After gastrectomy

Note: Some patients with this condition may never return to work.

Case Management Directives (refer to the original guideline for detailed recommendations)

Case Initiation

Establish Case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- See Chemotherapy Chart in the original guideline document.
- The American Joint Committee on Cancer encourages use of the "TNM" classification system (T=primary tumor size; N=lymph node involvement; M=metastasis).
- Provide contact information for local and national support groups.

Coordinate Care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity Deficit

- Document activity alteration as none, mild, moderate, severe, dependent, or bed-bound [based on most recent performance status] and interventions required.

Chemotherapy Intolerance

- Assess status, acute versus chronic, of toxic side effects on rapidly growing tissues, including bone marrow, epithelium, hair, sperm, and document intervention recommended.

Hemodynamic Instability

- Document bleeding complications, severity, and intervention recommended.

Immune Compromised

- Document establishment of protective isolation measures for a white blood cells count (WBC) less than 1,000/mm^3, implying dangerous susceptibly to infection.

Inadequate Nutrition

- Instruct that although esophagus to jejunum anastomosis re-establishes GI continuity, eating regular meals may be delayed for up to six months.
- Explain that if organ metastasis or obstruction occurs or if dysphagia persists, palliative tumor resection may be performed. See Intracorp Resection (Colectomy, Colostomy, Ileostomy) Procedure Guidelines.
- Report vasomotor response symptoms (those occurring 10 to 90 minutes after eating) and severity to agency nurse and/or treating physician.
- Monitor dysphagia after truncal vagotomy (possible esophageal trauma) and regurgitation after any gastric surgery.
- Assess need for ongoing parenteral vitamin B_{12} after total gastrectomy. See Intracorp Gastrectomy Guideline.
- Use optimal goal of remaining within 10% of pretreatment weight to document hydration and nutrition deficit as mild, moderate, severe and response needed.

Mental and Emotional Alteration

- Inform remorseful patient that early detection was unlikely.
- Ensure accurate diagnosis of any change in mental status.
- Document baseline or optimal mental and emotional functioning and their alterations due to cancer presence, comorbidity, surgery, or treatments.

- Assess and respond appropriately to the degree of debility caused by alterations listed in the original guideline document through benefit coordination or community resource activation.

Pain Control

- Document optimal pain management by characterizing severity and interventions undertaken to remedy or manage pain.

Oncologic Emergencies

- Immediately report to the surgeon or activate emergency medical technician (EMT) system as needed for abdominal distention and rigidity (possible obstruction or perforation); covert or overt bleeding (such as hematemesis or melena); decreased bowel motility (possible paralytic ileus); fistula formation; infection (intraperitoneal or wound); rapid gastric dumping (possible anorexia); sepsis (possible peritonitis or abscess); sweat gland dumping of fat (steatorrhea); wound dehiscence.
- Document presence of or developing oncologic emergencies and report to attending physician, surgeon, or activate EMT system as necessary.

Radiation Intolerance

- Document presence and severity of radiation side effects.
- Initiate early interventions for complications of radiation therapy.

Respiratory Instability

- Document respiratory deficit as mild, moderate, severe, and dependent, and respiratory rehabilitation enhancement measures.

Skin Integrity Deficit

- Document severity of skin integrity disruption.

Terminal Care

- Document optimal comfort measures and palliative care initiatives.

Discharge

Discharge from Case Management (CM)

- Document return to independence or stabilized functional status and closing conversations with patient, caregiver, physician, pharmacist, and care providers.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of gastric cancer that assist medical management leaders in making appropriate benefit coverage determinations

POTENTIAL HARMS

Refer to the Case Management Focus section of the "Major Recommendations" field for information on potential complications and strategies to address them, or refer to the original guideline document.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Gastric cancer. Philadelphia (PA): Intracorp; 2005. Various p. [18 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2005)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Intracorp guidelines are available for a licensing fee via a password protected, secure Web site at www.intracorp.com.

Reprints of complete guideline content may be purchased for $35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 25, 2005. The information was verified by the guideline developer on June 7, 2005.

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